

**PATENT COOPERATION TREATY**  
**PCT**  
**INTERNATIONAL PRELIMINARY EXAMINATION REPORT**

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 12258150/JMS/PXK/VXK	<b>FOR FURTHER ACTION</b>	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416).
International Application No. <b>PCT/AU2003/000892</b>	International Filing Date (day/month/year) 10 July 2003	Priority Date (day/month/year) 10 July 2002
International Patent Classification (IPC) or national classification and IPC Int. Cl. <sup>7</sup> G01N 33/68, 33/86, C12N 9/76, C12Q 1/66, 1/56, C07K 1/36, 17/02, 14/75		
Applicant CRYPTOME PHARMACEUTICALS LTD et al		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

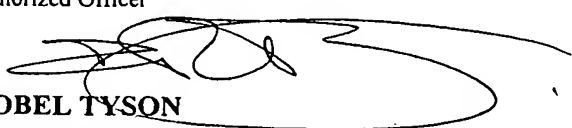
2. This REPORT consists of a total of 5 sheets, including this cover sheet.

☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of sheet(s).

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☒ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand 10 February 2004	Date of completion of the report 19 October 2004
Name and mailing address of the IPEA/AU. AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustalia.gov.au Facsimile No. (02) 6285 3929	Authorized Officer  <b>ISOBEL TYSON</b> Telephone No. (02) 6283 2281

**I. Basis of the report****1. With regard to the elements of the international application:\***

- ☒ the international application as originally filed.
- ☐ the description, pages , as originally filed,  
pages , filed with the demand,  
pages , received on with the letter of
- ☐ the claims, pages , as originally filed,  
pages , as amended (together with any statement) under Article 19,  
pages , filed with the demand,  
pages , received on with the letter of.
- ☐ the drawings, pages , as originally filed,  
pages , filed with the demand,  
pages , received on with the letter of
- ☐ the sequence listing part of the description:  
pages , as originally filed  
pages , filed with the demand  
pages , received on with the letter of

**2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.**

These elements were available or furnished to this Authority in the following language which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

**3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:**

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

**4. ☐ The amendments have resulted in the cancellation of:**

- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/fig.

**5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).\*\***

\* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

\*\* Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims 9-14, 16-24	YES
	Claims 1-8, 15, 25-28	NO
Inventive step (IS)	Claims 9-14, 16-24	YES
	Claims 1-8, 15, 25-28	NO
Industrial applicability (IA)	Claims 1-28	YES
	Claims	NO

2. Citations and explanations (Rule 70.7)

This report is based on the following documents:

- D1 = US 6358692 B1 (JINDAL et al), 19 March 2002
- D2 = US 6329146 B1 (CROOKE ET AL), 11 December 2001
- D3 = US 6428956 B1 (CROOKE ET AL), 6 August 2002
- D4 = US 6221626 B1 (BIENVENUT et al), 24 April 2001
- D5 = US 6495314 B1 (KENT et al), 17 December 2002

**NOVELTY (N) AND INVENTIVE STEP (IS):**

D1 discloses the elements of the invention including creation of a library by detection of bioactive peptides (column 7 lines 16 - 20) derived by enzymatic cleavage, chemical cleavage or physical digestion from a precursor protein or protein containing biological extract including a library of peptides, optionally screening, separating the library into fractions and screening the fractions for biological activity, optionally separating and screening subfractions and isolating and screening active fractions in several dimensions. The citation relates to screening a protein sample automatically and repetitively by screening for bioactivity (column 14 lines 21 - 25) against a bioactive target by various screening techniques, for example as discussed in column 8 lines 46 - column 9 line 5 and including the use of MALDI, see also Example 2F and column 37 line 26 - 31. The precursor protein (column 8 lines 1 - 10) may also be a naturally occurring protein - as claimed in claim 15 of the present application. The screening can be carried out by chromatography (claims 25 and 26). Hence **claims 1-8, 15 and 25-28** are not novel or inventive in the light of document D1.

D2 relates to the use of mass spectrometric methods for the simultaneous screening of multiple biomolecular targets and combinatorial libraries (column 7 lines 18 - 21) including the use of MALDI-MS (column 8 line 3, column 11 lines 53 - 56, column 13 lines 58 - column 15 line 10) and thus **claims 1-8 and 25-28** are not novel and not inventive (see column 7 lines 5 - 8, column 7 lines 53 - column 8 line 3, column 11 line 53 - column 12 line 4).

CONTINUED ON SUPPLEMENTAL SHEET:

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/AU2003/000892

## VI. Certain documents cited

## 1. Certain published documents (Rule 70.10)

Application No. Patent No.	Publication date (day/month/year)	Filing date (day/month/year)	Priority date ( valid claim) (day/month/year)
US 6428956 B1	6 August 2002	12 May 1998	2 March 1998
US 6495314 B1	17 December 2002	27 September 1996	27 September 1996

## 2. Non-written disclosures (Rule 70.9)

Kind of non-written disclosure	Date of non-written disclosure (day/month/year)	Date of written disclosure referring to non-written disclosure (day/month/year)
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**Supplemental Box**

(To be used when the space in any of the preceding boxes is not sufficient)

**Continuation of Box V(2):**

D3 is published after the priority date of the application of 10 July 2002, see Box VI, but would otherwise deprive claims 1-8 and 25-28 of novelty and invention (see column 5 lines 21 - 24, column 6 lines 59 - 66, column 7 lines 40 - 60).

D4 relates primarily to the use of a gel for separation and screening using an enzymatic cleavage and is thus background art.

D5 is published after the priority date of the proposed invention, see Box VI, but contains a description of the use of MALDI in protein signature analysis used to identify active and inactive areas of a single protein and is thus background art.

**INDUSTRIAL APPLICABILITY (IA):**

No issues of lack of industrial applicability arise.